DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Reliance Medical Systems, LLC
Mr. Bret Berry
Member-Manager
P.O. Box 1693
Bountiful, Utah 84010

April 29, 2015

Re: K142867
Trade/Device Name: Reliance Posterior Cervical-Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: February 13, 2015
Received: April 1, 2015

Dear Mr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142867

Device Name
Reliance Posterior Cervical-Thoracic System

Indications for Use *(Describe)*
The Reliance Posterior Cervical-Thoracic System is intended to promote fusion of the cervical spine and cervicothoracic junction (C1-T3), and is indicated for the following:
• ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
• Spondylolisthesis
• Spinal stenosis
• Fracture/dislocation
• Revision of previous cervical spine surgery
• Tumors

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for anchoring the system only. They are not intended to be placed in the cervical spine.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

WARNING: This device is not approved for screw attachment or fixation to the posterior element(pedicles) of the cervical, thoracic (T4–T12), or lumbar spine. Pedicle screws are intended for placement only in T1-T3 as a means of anchoring the system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary **10/28/2014**

Reliance Medical Systems, LLC
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Telephone: 801-295-3280
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Contact: Bret Berry
Member-Manager

Common or Usual Name:	Spinal Fixation Device
Proposed Proprietary or Trade Name:	Reliance Posterior Cervical-Thoracic System
Classification Name:	Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050)
Product Code:	KWP

Substantial Equivalence

The **Reliance Posterior Cervical-Thoracic System** is substantially equivalent to itself (K122292), primary predicate device and the secondary predicate device, Synthes Synapse System & OC Fusion System (K141897), in terms of material, intended use, levels of attachment, size range, and strength.

Device Description

The Reliance Posterior Cervical-Thoracic System is comprised of implant and instrument components. The implant component, the Reliance Posterior Cervical-Thoracic device, consists of posterior attachment elements with a set screw and rod. The Posterior Cervical-Thoracic pedicle screw component is offered in a mono-axial configuration. In addition to this components, there are also ancillary components such as hooks, connectors, cross-links, and lateral offset connectors. There are also thoracic poly-axial screw components. Furthermore, the Reliance Posterior Cervical-Thoracic System has a variety of configurations to meet specific patients' needs.

The Reliance Posterior Cervical-Thoracic instrument components include screw drivers, drill guides, plate holders, and drill bits. These instruments are manufactured from stainless steel, high grade plastic, and silicone rubber. There are also instrument trays that house these components.

Intended Use/Indications for Use

The **Reliance Posterior Cervical-Thoracic System** is intended to promote fusion of the cervical spine and cervicothoracic junction (C1-T3), and is indicated for the following:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for anchoring the system only. They are not intended to be placed in the cervical spine.

Hooks and Rods

The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4–T12), or lumbar spine. Pedicle screws are intended for placement only in T1-T3 as a means of anchoring the system.

Performance Data and Substantial Equivalence Discussion

The Reliance Posterior Cervical-Thoracic System has undergone Non-Clinical Testing including Static Compressive, Static Torsion, Dynamic Compressive and Dynamic Torsion in accordance with ASTM F1717. The Reliance Posterior Cervical-Thoracic System is substantially equivalent to the predicate devices. Additionally, the Reliance Posterior Cervical-Thoracic System is also substantially equivalent to the predicate devices in terms of sterilization and biocompatibility.